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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,080	02/20/2004	Todd Manegold	3071.TDM	6264

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NATIONAL STARCH AND CHEMICAL COMPANY
P.O. BOX 6500
BRIDGEWATER, NJ 08807-3300

EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
10/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@nstarch.com

Office Action Summary	Application No.	Applicant(s)	
	10/783,080	MANEGOLD ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicants Arguments/Remarks and amended claims filed on 08/03/2007 is acknowledged.

Claims 1 and 12 have been amended.

Amended Claims 1-20 are pending in this application and claims 1-20 will be prosecuted on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 7-10 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-10 and 14 recite the limitation "at least about" with respect to the amounts of caffeine, percentages of caffeine and modified starch. The phrase "at least about" does not define the specific range limitations, as such rendering the claims indefinite. The term "atleast" denotes a specific limit where as about is an approximation.

Response to Arguments

4. Applicant's arguments filed 08/03/2007 have been fully considered but they are not persuasive. Applicants argue that the term "atleast about 'is not indefinite. This argument is not persuasive because as stated above the term" atleast is an amount which is specific in nature whereas 'about is an approximation. As such, the limits are not specific. Hence the rejection is maintained.

The following are new rejections necessitated by Applicants Amendments.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-9 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US patent No. 5,599,554) in view of Kulkarni et al. (WO 2004/096174 A1). Majeti discloses transdermally or transmucosally administrable composition in the form of mucoadhesive or bioadhesive films for the treatment and /or smoking withdrawal symptoms (abstract and column 2, lines 18-23 and column 3, lines 17-20). The composition comprises caffeine, which is slightly soluble in water and alcohol (column 3,

lines 17-20). The various amounts of caffeine are used in the dosage form are listed on column 4, lines 10-23). Majeti further suggests that the amount of caffeine and frequency of administration may vary depending on the carrier and the personal needs of the user (column4, lines 24-26). Majeti discloses that a variety of additional pharmaceutically acceptable ingredients may be added such as disintegration agents (column 6, lines 25-27). The teachings of Majeti have been discussed above. Majeti does not specifically disclose the claimed percentage or amount of caffeine in the composition. It is to be noted that with respect to the claimed percentages and amount of caffeine, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by performing manipulative experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The teachings of majeti have been discussed above. Majeti does not disclose dispersing an active ingredient in an aqueous environment. However, Kulkarni discloses fast dissolving orally consumable films containing pharmaceutically active agents (abstract). On pages 20-40 in specific examples, kulkarni discloses dextromethorphan HBr mixed and dissolved in water to yield an aqueous phase. On page 2 Kulkarni discloses that the invention discloses a method of preparing a supple, non-self adhering film especially suitable for oral delivery of active ingredient.

It would have been thus obvious to the one of ordinary skilled in the art to include the step/method of dissolving the active ingredient in aqueous phase based on the teachings of kulkarni and combine it with the teachings of Majeti et al. in order to achieve the claimed orally dissolvable film. A skilled artisan would have been motivated to prepare an active containing dissolvable film based on the teachings and guidance provided by Kulkarni and Majeti et al. with a reasonable expectation of success.

7. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballard et al. (US Pg Pub. 2005/0013847 A1)) in view of Kulkarni et al. (WO 2004/096174 A1).

Ballard et al. discloses a delivery system comprising a homogenous, thermoreversible gel film comprising film formers, active substance, bulking agent and pH controlling agent along with the process of manufacture of such films (abstract and page 1 paragraph [0002]). Ballard et al. disclose variety of film forming agents which includes modified starches (see page 1 paragraph [0004 and page 2, paragraph [0021]). Various modified starches are listed on page 3, paragraph [0024] including the claimed hydroxylpropylated starches. The films as disclosed contain active substances such as oral care agent, a breath freshening agent, a pharmaceutical agent, a nutraceutical, vitamin, a flavorant or a food (see page 2 paragraph [0018] and claim 2). Ballard et al. further disclose that the water content in the film ranges from 5-15% (page 3, paragraph [0028]). The process of manufacturing which involves mixing, coating, drying and molding or casting into films have been detailed on page 3 paragraph [0031] and [0044].

Although Ballard et al. do not specifically teach the claimed drug solubility, since they teach generic "pharmaceutical agent" and also "vitamins", which then includes lipophilic (vitamin A, E, D and K) compounds also, it would have been obvious to one of ordinary skill in the art to select these lipophilic compounds with low solubility from the teachings of Ballard et al. with a reasonable expectation of success.

The teachings of Ballard have been discussed above. Ballard does not disclose dispersing an active ingredient in an aqueous environment. However, Kulkarni discloses fast dissolving orally consumable films containing pharmaceutically active agents (abstract). On pages 20-40 in specific examples, kulkarni discloses dextromethorphan HBr mixed and dissolved in water to yield an aqueous phase. On page 2 Kulkarni discloses that the invention discloses a method of preparing a supple, non-self adhering film especially suitable for oral delivery of active ingredient.

It would have been thus obvious to the one of ordinary skilled in the art to include the step/method of dissolving the active ingredient in aqueous phase based on the teachings of kulkarni and combine it with the teachings of Ballard et al. in order to achieve the claimed orally dissolvable film. A skilled artisan would have been motivated to prepare an active containing dissolvable film based on the teachings and guidance provided by Kulkarni and Ballard et al. with a reasonable expectation of success.

Ballard does not specifically disclose the claimed percentage or amount of caffeine in the composition. It is to be noted that with respect to the claimed percentages and amount of caffeine, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the

invention was made by performing manipulative experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

8. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit 1615

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600